

**MINUTES**  
**KENTUCKY BOARD OF PHARMACY**  
Spindletop Administration Building, Suite 302  
2624 Research Park Dr.  
Lexington, Kentucky

Dec. 13, 2006

**CALL TO ORDER:** A regular meeting of the Kentucky Board of Pharmacy was held at the Board Office at Spindletop Administration Building, Suite 302, 2624 Research Park Dr., Lexington, Kentucky. President Naseman called the meeting to order at 9:14 a.m.

Members present: Greg Naseman, Peter Orzali, Mike Leake, Catherine Shely, Sandy Simpson and Patricia Thornbury. Staff: Michael Bureson, Executive Director; Jeffrey L. Osman, Pharmacy Inspections and Investigations Coordinator; Steve Hart, Katie Busroe and Phil Losch, Pharmacy and Drug Inspectors; and Lisa Atha, Executive Secretary. Guests: Brian Fingerson, Pharmacist Recovery Network Committee; Ralph Bouvette and Trey Hienemen, APSC; Chris Killmeier, Walgreens; Jan Gould, Kentucky Retail Federation; Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services; Brad Hall, KPhA; Michael Wyatt, Cardinal; Shannon Girard, appearance; Jack Girard; William Thornbury; and Christina Westcroft, University of Kentucky College of Pharmacy PY4 student. Melanie Curtis, Court Reporter, recorded the meeting.

**MINUTES:** On motion by Dr. Shely, seconded by Mr. Leake and passed unanimously, the Minutes of October 20, 2006 were adopted.

On motion by Mr. Orzali, seconded by Dr. Shely and passed unanimously, the Minutes of the Board Retreat October 21-22, 2006 were adopted, as amended.

**APPEARANCES:** **Shannon Girard** was sworn in by Melanie Curtis, Court Reporter. Ms. Girard appeared before the Board asking for reinstatement of her Kentucky pharmacist's license after a one year suspension. Ms. Girard gave a brief overview of the circumstances leading to the loss of her license and her activities over the past year. Mr. Leake moved to allow Ms. Girard's license be reinstated with the stipulations as follows: 5 years probation; maximum hours of work: 40 hrs/wk or 80 hrs/2wk, no more than 12 hour shift in 24 hour period with no overtime, can petition for overtime after 3 years; shall not serve as pharmacist-in-charge; may not have power of attorney; shall not be a preceptor; must provide copy of Agreed Order to all employers; must enter into an aftercare contract with PRN Committee, to include drug counselor if indicated; must submit signed release for Board access to all medical records; must attend NA/AA meetings no less than 3 times per week; must submit to the Board written monthly reports of all NA/AA meetings; must submit to random observed drug screens; shall be subject to bi-annual inspections by the Board at all places of employment, with audits to be conducted if necessary, the cost of each inspection not to exceed \$500; perpetual inventory of Scheduled II drugs to be required at each place of employment; shall not ingest any mood altering substances whether legend or nonlegend medications including alcohol; notification to the Board within 3 days of all legend and nonlegend drugs prescribed/ingested; Board or Board President to approve all pharmacies/worksites and schedule prior to employment; shall not dispense any drugs for herself or her family members; shall obtain all prescriptions and those of family members at pharmacy designated in writing to the Board; attendance at the University of Utah School on Alcoholism and Other Drug Dependencies, the South Eastern PRN meeting, or the CAPTASA

conference within one year; provide the Board and PRN Committee with a written self-performance evaluation monthly; any violation of state and/or federal pharmacy or drug laws constitutes violation of Agreed Order and may result in an emergency suspension of pharmacist's license. The Agreed Order shall be reported to NABP. Mr. Orzali seconded, and the motion passed unanimously.

**INTERAGENCY:** Paula York, Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services, gave an update on changes to 902 KAR 55:110, the regulation governing the Kentucky All Schedule Prescription Electronic Reporting (KASPER). Pharmacies shall now transmit KASPER data every 8 days instead of 16 days. Pharmacies can no longer use all nine's as a patient identifier, a Social Security number or driver's license number must be given by the patient. In the case of a child without a Social Security number, the parent's Social Security number or driver's license number should be used.

There is a public hearing on December 21, 2006 regarding the proposal on a schedule change of tramadol to a Schedule III drug, and written comment will be received until January 2, 2006. Drug Enforcement and Professional Practices Branch is asking for antidotal information and people willing to testify as to the abuse of tramadol.

Mr. Orzali moved to direct the Executive Director write a letter to Dave Sallengs, Branch Manager of the Drug Enforcement and Professional Practices Branch, asking that the Kentucky Board of Pharmacy be informed in writing of any regulation changes. Ms. Thornbury seconded and the motion passed unanimously.

Brad Hall, Kentucky Pharmacists Association (KPhA), informed the Board that KPhA would be announcing the association's 2007 legislative agenda on December 14, 2006. Mr. Burleson is to e-mail the agenda to the Board members. KPhA is working with the Cabinet for Health and Family Services on emergency preparedness for a pandemic bird flu outbreak.

**BOARD REPORTS:** **President.** 1) President Naseman began a discussion of 201 KAR 2:095, dispensing responsibilities. According to the Drug Enforcement and Professional Practices Branch, an intern is not prohibited from taking a verbal controlled substance prescription via the telephone after the intern has successfully completed his or her first professional year coursework of a Bachelor's of Science in pharmacy or Doctor of Pharmacy degree program and is under appropriate supervision. Mr. Orzali moved to implement a Board policy that the transfer of a prescription is a professional act; therefore an intern may transfer a prescription after the intern has successfully completed his or her first professional year coursework of a Bachelor's of Science in pharmacy or Doctor of Pharmacy degree program and is under the appropriate supervision. The supervising pharmacist is responsible for all the actions of the pharmacy intern. Ms. Thornbury seconded and the motion passed unanimously. 2) President Naseman reported that the PRN Ad Hoc Committee is continuing to make significant progress and he thanked Katie Busroe for chairing the committee.

**Board Executive Director.** 1) MARS reports included for October and November 2006. 2) Wal-Mart sent a request for an appearance regarding automated will call bins. Ms. Thornbury directed Mr. Burleson to gather information regarding automated will call bins from other states, present the information to the Board for the January 10, 2007 Board meeting, and have Wal-Mart appear at the March 2007 Board meeting if needed. 3) It has become a problem to get a place for the January 10, 2007 Board meeting to include University of Kentucky third year pharmacy students as part of the audience. A suitable place with adequate parking can not be found for a

reasonable cost. Brad Hall of KPhA offered to sponsor the meeting for the students, if it can be worked out with the University.

**Board Staff.** Phil Losch thanked the Board for allowing him to go to the ASHP mid year meeting, it was very informative.

Katie Busroe thanked the Board for allowing her to go to the NASCSA meeting. The Combat Methamphetamine Epidemic Act requires pharmacies to keep an electronic record or written record of all ephedrine, pseudoephedrine, and phenylpropanolamine sales. According to the Drug Enforcement Administration, the written record must be in a bound log in which it can be determined if pages have been removed. This is a log with a spine not a three ring binder or a spiral bound notebook. A statement must be on the log book or posted in the pharmacy outlining the penalties of fraudulently obtaining one of these substances.

**PRN Chairperson/Brian Fingerson.** The CAPTASA meeting will be held January 26 and 27, 2007 at the Embassy Suites in Lexington, Kentucky.

Mr. Leake moved that in the instance of a first time offence, any pharmacist that violates his or her PRN Agreement by failing to submit the required paperwork be required to appear before the PRN Committee with a letter of admonishment sent to the pharmacist from the Board. Dr. Shely seconded, and the motion passed unanimously.

#### **CURRENT/PENDING CASES:**

Ms. Thornbury moved for acceptance and entry of the proposed Agreed Orders as written. Ms. Simpson seconded, and the motion passed unanimously.

**Case No. 05-0046A; Case No.05-0052B; Case No.06-0012A; Case No. 06-0030B; Case No. 06-0052; Case No. 06-0058A; Case No. 06-0060; Case No. 06-0061; Case No. 06-0061Z; Case No. 06-0062; Case No. 06-0063B; Case No. 06-0070; Case No. 06-0071; Case No. 06-0073; Case No. 06-0074; Case No.06-0077; Case No.06-0078; Case No. 06-0079; Case No. 06-0082; Case No. 06-0083; Case No. 06-0088A; Case No. 06-0088B; Case No. 06-0090A; Case No. 06-0091; Case No. 06-0092; Case No. 06-0093; Case No.06-0094; Case No. 06-0095; Case No. 06-0096; Case No. 06-0098; Case No. 06-0099; Case No. 06-0101; and Case No. 06-0102.**

#### **CASE REVIEW COMMITTEE:**

Mr. Orzali moved for acceptance of the Case Review Committee recommendations for the following case reports. Dr. Shely seconded, and the motion passed unanimously.

**Case No. 04-0097A (revisit).** It is alleged that the permit holder sold misbranded drugs; the Board has been cooperating with the FDA on this case and has been awaiting a decision of the U.S. Attorney, as to any action to be taken against the pharmacy and/or pharmacist. NEW INFORMATION: Pharmacist died on 9/17/06, and pharmacy was sold on 10/10/06. Alleged violation of law: KRS 217.065. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 04-0097B (revisit).** It is alleged that the pharmacist dispensed misbranded drugs; the Board has been cooperating with the FDA on this case and has been awaiting a decision of the U.S. Attorney, as to any action to be taken against the pharmacy and/or pharmacist. NEW INFORMATION: Pharmacist died on 9/17/06, and pharmacy was sold on 10/10/06. Alleged violation of law: KRS 217.065. CRC Recommendation: Case is dismissed.

**Case No. 05-0101A.** Pharmacy permit holder allegedly surrendered Kentucky pharmacy permit as part of an agreement with the Federal government while pharmacist is awaiting trial. Alleged violations of law: KRS 315.121(1)(a), (2)(c) (d) (e) and (f). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

**Case No. 05-0101B (revisit).** Pharmacist allegedly engaged in unprofessional and unethical conduct by trafficking in a controlled substance, a Class D. felony. NEW INFORMATION: Pharmacist surrendered Kentucky pharmacist's license and pharmacy permit as part of an agreement with the Federal government while pharmacist is awaiting trial. Alleged violations of law: KRS 315.121(1)(a), (2)(c) (d) (e) and (f). CRC Recommendation: There is sufficient evidence developed and the investigator is directed to conduct further investigation.

**Case No. 06-0002.** Pharmacist is allegedly impaired and diverted controlled substances. Pharmacist allegedly violated her PRN agreement. Alleged violations of law: KRS 315.121(1)(b), (2)(d)(e). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0064.** Pharmacist allegedly engaged in unprofessional and unethical conduct by committing a medication error. A patient received another patient's medication. The patient was to receive chlorpromazine 50mg but instead received Klor-Con 10mEq. The patient took one Klor-Con 10mEq and allegedly became violently ill with a rapid heart beat. The Klor-Con 10mEq also allegedly exacerbated the patient's Lupus. Alleged violations of law: KRS 315-121 (1)(a) and (2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0065.** Pharmacist is allegedly impaired and diverted controlled substances. Alleged violations of law: KRS 315-121(1)(b) and (2)(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0081.** Pharmacist allegedly engaged in unprofessional conduct by committing a medication error. A prescription was written for hydrocodone/acetaminophen 10mg/650mg, quantity 120. On two occasions, the patient allegedly received less than 120 tablets. Alleged violations of law: KRS 315.121 (1)(a) and (2)(d) and KRS 217.065 (1). CRC Recommendation: Case is dismissed.

**Case No. 06-0103A.** Pharmacy permit holder allegedly committed a medication error by dispensing less than the quantity prescribed. Alleged violation of law: KRS 315.121 (2)(h). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0103B.** Pharmacist allegedly committed a medication error by dispensing less than the quantity prescribed. Alleged violation of law: KRS 315.121 (2)(h). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0104A.** Pharmacy permit holder allegedly committed Medicaid fraud by billing injectable prescription drugs and not dispensing them. It is also alleged that prescriptions are filled more frequently than prescribed in order to obtain additional fees. Additionally, it is alleged that the pharmacist has left technicians alone in the pharmacy without a pharmacist being present. Alleged violations of law: KRS 315.121(2) and 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0104B.** Pharmacist allegedly committed Medicaid fraud by billing injectable Rx drugs and not dispensing them. It is also alleged that prescriptions are filled more frequently than prescribed in order to obtain additional fees. Additionally, it is alleged that the pharmacist has left technicians alone in the pharmacy without a pharmacist being present. Alleged violations of law: KRS 315.121(2) and 201 KAR 2:100 Section 1. CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0108A.** Pharmacy permit holder allegedly sold a misbranded drug. Alleged violation of law: KRS 315-121 (2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0108B.** Pharmacist allegedly committed a medication error. Alleged violation of law: KRS 315-121 (2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0110A.** Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate and consultant pharmacist allegedly failed to conduct quarterly inspections. Alleged violations of law: KRS 315.035(1)(4) and 201 KAR 201 2:225 Section 2(1)(b). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0110B.** Special limited medical gas pharmacy permit holder allegedly failed to renew permit in a timely manner and continued to operate and consultant pharmacist allegedly failed to conduct quarterly inspections. Alleged violations of law: KRS 315.035(1)(4) and 201 KAR 201 2:225 Section 2(1)(b). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0111.** Pharmacist is allegedly unable to practice pharmacy with reasonable skill, competence, and safety to the public due to impairment. Pharmacist allegedly ingested controlled substances for which prescription drug orders are required, without having first received prescription drug orders for the drugs. Pharmacist has been indicted on eleven felony drug counts. Alleged violations of law: KRS 315.121 1(b) and 2(f). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0116A.** Pharmacy permit holder allegedly committed a medication error, a prescription for Rondec DM drops with directions of  $\frac{3}{4}$  dropper four times daily as needed was prescribed. The patient received a generic formulation of the syrup with the directions of  $\frac{3}{4}$  teaspoonful four times daily as needed. Alleged violation of law: KRS 315.121 (2)(d). CRC Recommendation: There is insufficient evidence of a violation to warrant disciplinary action and the case is closed without prejudice.

**Case No. 06-0116B.** Pharmacist allegedly committed a medication error, a prescription for Rondec DM drops with directions of  $\frac{3}{4}$  dropper four times daily as needed was prescribed. The patient received a generic formulation of the syrup with the directions of  $\frac{3}{4}$  teaspoonful four times daily as needed. Alleged violation of law: KRS 315.121 (2)(d). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0117.** Manufacturer allegedly failed to renew permit in a timely manner and continued to operate as a manufacturer by transfilling oxygen. Alleged violation of law: KRS 315.036(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0118.** Pharmacist allegedly failed to complete 0.1 CEU of the required 1.5 CEU's of pharmacy continuing education in 2005. Alleged violations of law: KRS 315.065(2) and 201 KAR 2:015. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0119.** Special limited medical gas permit holder failed to notify the Board of closure. Alleged violation of law: 201 KAR 2:106 Sec 2. CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

**Case No. 06-0120.** Manufacturer permit holder allegedly failed to renew permit in a timely manner and continued to operate as a manufacturer by filling medical oxygen tanks. Alleged violation of law: KRS 315-036(1). CRC Recommendation: There is sufficient evidence of a violation to warrant disciplinary action and the Executive Director is directed to attempt resolution through an Agreed Order and, if unsuccessful, to proceed with either an Administrative Conference, if requested, or the issuance of a Formal Complaint and Notice of Hearing.

### **CORRESPONDENCE/COMMUNICATIONS:**

**St Joseph Hospital** requested that Dana Foster be allowed dual pharmacist-in-charge for St. Joseph East Pharmacy and Continuing Care Hospital Pharmacy. Ms. Thornbury moved to approve this request, Mr. Leake seconded, and the motion passed unanimously.

**Bluegrass Pharmacy** requested that Gary Russell be allowed to be pharmacist-in-charge for three permits, Bluegrass Pharmacy, Bluegrass I.V. Care, and Bluegrass LTC Pharmacy. Mr. Orzali moved to approve this request, Ms. Simpson seconded, and the motion passed unanimously.

**Cardinal Hill Hospital** requested that Scott Ferguson be allowed dual pharmacist-in-charge for Cardinal Hill Hospital Outpatient Pharmacy and Cardinal Hill Hospital Inpatient Pharmacy. Dr. Shely moved to approve this request, Mr. Leake seconded, and the motion passed unanimously.

**Jill Rempe** requested suspension of her Probation in accordance with her Agreed Order of Reciprocity with Conditions. Mr. Orzali moved to approve this request, Dr. Shely seconded, and the motion passed unanimously.

**EX 06-02,** Expungement request. Ms. Thornbury moved to approve the expungement from 1999, Mr. Orzali seconded, and the motion passed unanimously.

**Pharmacy Alternatives** requested an exemption from printing daily logs and instead use a document to be signed daily by each pharmacist on duty attesting to the accuracy of that day's business. Ms. Thornbury moved to approve the request with the following wordings and conditions: it must be a daily signature log that a pharmacist signs at the end of his/her shift and it must state-"I attest to the fact that the information entered into the (computer) system this day, which bears my initials, has been reviewed by me and is correct as entered." Ms. Simpson seconded and the motion passed unanimously.

**John Ising** requested he be allowed to be dual pharmacist-in-charge at Rite Aid Pharmacy #4644 and Diabetes Care and Education Pharmacy. Mr. Ising spends about one hour one day per week at the Diabetes Care and Education Pharmacy filling insulin prescriptions. Ms. Thornbury moved to approve this request, Mr. Leake seconded, and the motion passed unanimously.

**National Respiratory** requested that Linda Schmidt be allowed dual pharmacist-in-charge for National Respiratory Services and Premier Home Care. Ms. Thornbury moved to approve this request, Ms. Simpson seconded, and the motion passed unanimously.

**Integrity Healthcare** requested that all Kentucky facilities be granted a waiver for the equipment requirements including having a Class III prescription balance or Class A prescription balance with weights, graduates, mortar and pestles, funnel with filter paper, heating unit, and ointment slab or papers. Ms. Thornbury moved to deny the request because the Board does not

license compounding pharmacies separately from other pharmacies, nor is there distinction made based on the type of compounding, high, medium, or low risk, preformed at the pharmacy. Mr. Orzali seconded, and the motion passed unanimously.

**RxCrossroads** requested approval of an electronic bulk transfer of prescriptions. Dr. Shely moved to approve this request, Mr. Leake seconded and the motion passed unanimously.

**Tri-care Pharmacy** requested a waiver on the space required in a nuclear pharmacy from the 120 square foot minimum space required by 201 KAR 2:215 to an 80 square foot area. The Radiation Control Branch of the Cabinet for Health and Family Services has issued Tri-care Pharmacy a radioactive materials license. Mr. Orzali moved to approve this request based on current practice, but if circumstances change including Tri-care Pharmacy applying for any amendments to the radioactive materials license from the Radiation Control Branch, the Board of Pharmacy must be informed and the Board may reconsider the space allowance. Dr. Shely seconded and the motion passed unanimously.

**PharmacistCARE** requested an equipment waiver. Mr. Orzali moved to accept this request, Ms. Thornbury seconded and the motion passed unanimously.

**LEGISLATION/REGULATIONS:** A copy of the revised Technician Bill was distributed for the Board members to review with discussion to take place at the January 10, 2007 Board meeting.

**CONTINUING EDUCATION:** Ms. Thornbury moved to accept the continuing education programs 06-54 through 06-57 as recommended. Mr. Orzali seconded, and the motion passed unanimously.

**OLD BUSINESS:** Discussion of the central fill/refill/processing regulations and wholesaler/pedigree statute and regulation will take place at the January 10, 2007 Board meeting.

**NEW BUSINESS:** Board Elections: President Naseman opened the floor for nominations for 2007 President Elect. Dr. Shely nominated Mike Leake for President Elect. No other nominations were made. Vote was by secret ballot, counted by Inspectors Philip Losch and Steve Hart. The vote was 5 in favor of Mike Leake and 1 abstention.

Mr. Orzali was sworn in as President of the Kentucky Board of Pharmacy for 2007.

**ADJOURNMENT:** On motion by Mr. Leake, seconded by Ms. Simpson, and passed unanimously, President Naseman adjourned the meeting at 12:40 p.m. The next regularly scheduled Board meeting is scheduled to begin at 9:00 a.m. on January 10, 2006 at a place to be announced.



